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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,884

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Jonathan Lightner

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EXAMINER

MCCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

01/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/553,884

Applicant(s)

LIGHTNER ET AL.

Examiner

Elizabeth F. McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 12-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed October 20, 2008 has been entered.

Claims 9-11 are cancelled.

Claims 1, 5 and 6 are currently amended.

Claims 12-17 are newly submitted.

Claim Objections

Claim 15 is objected to for the omission of the word “of” between “method” and “claim”.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8 and 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 1 and 6, and claims 2-5, 7, 8 and 12-17 dependent thereon, are indefinite in the recitation of “high oil phenotype relative to a plant of the same species that does not comprise the plant transformation vector” and “altered oil content phenotype relative to a plant of the same species that does not comprise the plant transformation vector”, given that the oil content of a plant species can vary significantly depending on the variety and that growth conditions, for example. Therefore, it is unclear what the oil content would be compared to.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 6, and claims 2-5, 7, 8 and 12-17 dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection. The recitation of "high oil phenotype relative to a plant of the same species that does not comprise the plant transformation vector" and "altered oil content phenotype relative to a plant of the same species that does not comprise the plant transformation vector" appear to be new matter, as the Examiner could not find this phrase or the same concept in the specification, as filed. In addition, this language was not found in any of the passages pointed to by applicant.

6. Claims 1-8 and 12-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to transgenic plants comprising a plant transformation vector comprising a sequence that encodes HIO103.1 polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or any sequences that encode polypeptides that are 95% identical to SEQ ID NO: 2 of HIO103.1 or complementary thereto, and wherein the plant has a high oil phenotype relative to control plants and methods of producing said transformed plant. However,

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the specification only provides a plant transformed with a nucleic acid encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 that when overexpressed produces a high oil phenotype in the plant. The specification does not identify any other sequences that produce a high oil or altered oil phenotype, including any sequences that encode polypeptides that are 95% identical to SEQ ID NO: 2 of HIO103.1 or complementary thereto.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

7. Applicants' arguments filed October 20, 2008 have been fully considered but they are not persuasive. Applicants argue that literal support is not required and the specification describes how to identify sequences that are 95% identical to SEQ ID NO: 2 and for determining a high oil phenotype. The Examiner maintains that the claims are broadly drawn to any plant species and to any plant having either a high oil phenotype or an altered oil phenotype that is transformed with a sequence that encodes or is complementary to SEQ ID NO: 2 or to a sequence that is 95% identical thereto. Applicants have claimed a broad genus, yet have only described an Arabidopsis plant that overexpresses a nucleic acid encoding SEQ ID NO: 2 that has a total oil content of 34.8% as compared to 32.5% for the control, or an increase of 35.6% as compared to a control of 33.5% (page 28 of the specification). The specification does not describe any other plant species that are transformed with any other sequences, including those complementary to sequences that encode SEQ ID NO: 2, that have any particular levels of oil.

Claim Rejections - 35 USC § 112

8. Claims 1-8 and 12-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plants comprising a plant transformation vector comprising a sequence that encodes the HIO103.1 polypeptide comprising the amino acid sequence of SEQ ID NO: 2, wherein the transgenic plant has a high oil phenotype, does not reasonably provide enablement for a transgenic plant comprising a plant transformation vector comprising a sequence that encodes the HIO103.1 polypeptide that has 95% identity to the amino acid sequence of SEQ ID NO: 2 or to any sequence complementary thereto, and wherein the transgenic plant has a high oil or altered oil phenotype. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons set forth in the last office action.

9. Applicants' arguments filed October 20, 2008 have been fully considered but they are not persuasive. Applicants argue that the specification teaches how to identify variants and how to test for high oil phenotypes in transgenic plants, and that the methods were known in the art. Applicants assert that claims 13, 14, 16 and 17 are enabled.

10. The Examiner maintains that the specification is only enabling for a plant transformed with a nucleic acid encoding SEQ ID NO: 2. The specification is not enabling for plants transformed with sequences complementary to those encoding SEQ ID NO: 2. Therefore, claims 13, 14, 16 and 17 are included in the enablement rejection. In addition, the Examiner maintains that there is a high level of unpredictability with regard to the functional activity of homologous sequences, as stated in the last office action. In the present case, the specification asserts that

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SEQ ID NO: 2 has sequence similarity to a transcription factor. The specification does not teach what modifications can be made to this sequence, such that high oil or altered oil phenotype would result in a plant transformed with the sequence. The present claims are broadly drawn to any plant species transformed with any sequence that encodes a polypeptide having at least 95% identity to SEQ ID NO: 2 or with any sequence complementary thereto, wherein the plant has a high oil or altered oil content. The Examiner maintains that it would require undue experimentation to practice the invention, as broadly claims for the reasons already of record.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/
Primary Examiner, Art Unit 1638